House Health Subcommittee Am. #1

Amendment No._____

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Signature of Sponsor

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AMEND Senate Bill No. 429 **House Bill No. 137***

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, is amended by deleting part 5 and substituting the following:

63-10-501.

As used in this part:

(1) "Anti-rejection drug" means a prescription drug that suppresses the immune system to prevent or reverse rejection of a transplanted organ;

(2) "Board" means the board of pharmacy;

(3) "Cancer drug" means a prescription drug that is used to treat any of the following:

(A) Cancer or the side effects of cancer; or

(B) The side effects of any prescription drug that is used to treat cancer or the side effects of cancer;

(4) "Controlled substance" means the same as defined in § 39-17-402;

(5) "Department" means the department of health;

(6) "Donor" means a person, a pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the board of pharmacy, who donates prescription drugs to a repository program approved pursuant to this part;

(7) "Eligible Individual" means an indigent person or an uninsured person who meets all other criteria established by board rule;

(8) "Indigent" means a person with an income that is below two hundred percent (200%) of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States department of health and human services;

(9) "Medical facility" means any of the following:

(A) A physician's office;

(B) A hospital;

(C) A health clinic;

(D) A nonprofit health clinic, which includes a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic, as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(E) A free clinic as defined in § 63-6-703;

(F) A charitable organization as defined in § 48-101-501; or

(G) A nursing home as defined in § 68-11-201;

(10) "Pharmacy" means a pharmacy as defined in § 63-10-204;

(11) "Prescription drug" means the same as defined in § 63-10-204, except the drug is only tablet or capsule form, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances and drugs covered by the risk evaluation and mitigation strategy program of the federal food and drug administration; and

(12) "Supplies" means the supplies necessary to administer the prescription drugs donated.

63-10-502.

(a)

(1) The department of health, in cooperation with the board of pharmacy, may promulgate rules to establish and enforce a prescription drug donation

repository program under which a person or organization may donate prescription drugs and supplies for use by an organization that has received a determination of exemption from the United States internal revenue service pursuant to 26 U.S.C. § 501(c)(3), and that meets eligibility criteria specified by rule for administering the program.

(2) Enforcement authority for rules promulgated pursuant to this part shall vest in the board of pharmacy.

(3) Organizations who administer a drug donation repository program shall report the following data to the department every year:

(A) Number of donors during the reporting year;

(B) Number of donations during the reporting year;

(C) List of prescription drugs and supplies donated during the reporting year;

(D) Number of people who received donations of prescription drugs or supplies during the reporting year;

(E) Total number of prescription drugs and supplies dispensed during the reporting year; and

(F) Total cost to eligible individuals who received donations during the reporting year.

(4) Rules promulgated pursuant to this part shall specify the format and method of transmission for data reported pursuant to subdivision (a)(3).

(b) Donations of prescription drugs and supplies under the program may be made directly to the repository program as required by the department or on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements established by the department. Donations of prescription drugs and supplies may be made by mail.

(c) A medical facility or pharmacy may charge an individual who receives a prescription drug or supplies a handling fee that does not exceed an amount established by rule.

(d) A medical facility or pharmacy that receives prescription drugs or supplies may distribute the prescription drugs or supplies to another eligible medical facility or pharmacy for use pursuant to the program.

(e) Participation in the program is voluntary.

63-10-503.

(a) A prescription drug or supplies may be accepted and dispensed under the prescription drug donation repository program if all of the following conditions are met:

(1) The prescription drug is in its original sealed and tamper-evident packaging. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose packaging remains intact;

(2) The prescription drug or supplies are inspected before the prescription drug or supplies are dispensed by a licensed pharmacist employed by or under contract with the medical facility or pharmacy, and the licensed pharmacist determines that the prescription drug or supplies are not adulterated or misbranded; and

(3) The prescription drug or supplies are prescribed by a healthcare practitioner for use by an eligible individual and are dispensed by a pharmacist.

(b) A prescription drug or supplies donated under this part shall not be resold.

(c)

(1) If a donor receives official notice of a recall of a prescription drug donated pursuant to this part, the donor shall make every effort, as required by rule, to notify the repository program to whom the drugs were donated of the recall.

(2) If an organization who is administering a drug repository program receives official notice of a recall of a prescription drug donated pursuant to this party, the organization shall make every effort as required by rule, to notify the pharmacy, medical facility, or patient, if known, to whom such donated drugs were dispensed, of the recall.

(3) Any donor or drug repository program who receives notice of a recall shall dispose of all recalled prescription drugs pursuant to board of pharmacy rules.

(d) A prescription drug dispensed through the prescription drug donation repository program is not eligible for reimbursement under the medical assistance program.

(e) The department shall adopt rules establishing all of the following:

(1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, including all of the following:

(A) Eligibility criteria for participation by medical facilities and pharmacies;

(B) Standards and procedures for accepting, safely storing, and dispensing donated prescription drugs and supplies;

(C) Standards and procedures for inspecting donated prescription drugs to determine if the prescription drugs are in their original sealed and tamper-evident packaging, or if the prescription drugs are in single-unit doses or blister packs and the outside packaging is opened, if the single-unit dose packaging remains intact; and

(D) Standards and procedures for inspecting donated prescription drugs and supplies to determine that the prescription drugs and supplies are not adulterated or misbranded;

(2) Additional eligibility criteria for indigent or uninsured persons;

(3) Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program;

(4) A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility;

(5) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program; and

(6) A list of prescription drugs that the prescription drug donation repository program will accept.

63-10-504.

(a) Except for gross negligence, willful misconduct, or bad faith, a drug manufacturer is not civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(b) Except as provided in subsection (d), a medical facility or another person who is not a drug manufacturer subject to subsection (a) is not civilly liable or subject to criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part except due to its own gross negligence, willful misconduct, or bad faith. The medical facility or other person who is not a drug manufacturer subject to subsection (a) is also exempt from disciplinary action related to the facility's or person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(c) Except for gross negligence, willful misconduct, or bad faith, the department of health or the board of pharmacy shall not be civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property resulting from matters

related to the donation, acceptance, distribution, or dispensing of a prescription drug donated pursuant to this part.

(d) The immunity and exemption provided in subsections (b) and (c) do not extend to the following:

(1) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(2) Acts or omissions outside the scope of the program.

63-10-505.

This part shall not restrict the use of samples by a physician or other person legally authorized to prescribe drugs pursuant to this title during the course of the physician's or other person's duties at a medical facility or pharmacy.

63-10-506.

This part does not authorize the resale of prescription drugs by any person.

63-10-507.

A medical facility or pharmacy may not dispense a prescription drug after the expiration date of the drug.

63-10-508.

Notwithstanding this title or title 68, or any rule, a long-term care facility licensed under title 68 may donate prescription drugs to the repository program established by this part.

63-10-509.

The department of health, in consultation with the board, is authorized to promulgate rules to effectuate the purposes of this part. The rules shall be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

63-10-510.

Notwithstanding this part or the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, any rule promulgated to implement the provisions of this part shall be provided to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate by the secretary of state, after approval by the attorney general and reporter, at the same time the text of the rule is made available to the government operations committees of the senate and the house of representatives for purposes of conducting the review required by § 4-5-226 in order for the health committee of the house of representatives and the health and welfare committee of the senate to be afforded the opportunity to comment on the rule.

SECTION 2. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity shall not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end the provisions of this act shall be severable.

SECTION 3. For purposes of promulgating rules, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect on January 1, 2018, the public welfare requiring it.

House Health Subcommittee Am. #1

Amendment No._____

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Signature of Sponsor

AMEND Senate Bill No. 224* House Bill No. 334

by inserting the following new section immediately preceding the last section and renumbering the subsequent section accordingly:

SECTION ___. Tennessee Code Annotated, Section 63-1-502(5), is amended by adding immediately after the language "within the competency and training of the direct primary care physician" the following language:

or, if applicable, within the scope of practice of a chiropractic physician

House Health Subcommittee Am. #2

Amendment No._____

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AMEND Senate Bill No. 224* **House Bill No. 334**

by inserting the following new section immediately preceding the last section and renumbering the subsequent section accordingly:

SECTION ___. Nothing in this act authorizes a chiropractic physician to use a title other than the titles recognized in Tennessee Code Annotated, Section 63-1-109(a)(1).

House Health Subcommittee Am. #1

Amendment No._____

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Signature of Sponsor

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AMEND Senate Bill No. 313* **House Bill No. 387**

by deleting the language "and" at the end of subdivision (a)(1)(A), and deleting subdivision (a)(1)(B) of the amendatory language of Section 1 and substituting instead the following:

(B) "Diagnosis" means:

(i) The differential diagnosis of human ailments through examination and evaluation of patients and through diagnostic procedures necessary to clinically correlate a physical examination to a diagnostic impression;

(ii) The ordering of X-rays, advanced diagnostic imaging, and other diagnostic procedures;

(iii) The performance of X-rays and other non-invasive diagnostic procedures, as well as minimally invasive procedures for which the chiropractic physician has received training by an institution accredited by the Council on Chiropractic Education or its successor and which have been approved by the board of chiropractic examiners after consultation with the board of medical examiners; and

(iv) The collection of blood, urine, saliva, and hair for analysis; provided, however, venipuncture shall only be done by a phlebotomist or other person who is properly trained to draw blood;

(C) "Practice of chiropractic" means the diagnosis and treatment of patients, as defined in subdivisions (a)(1)(B) and (a)(1)(D); and .

(D) "Treatment" means:

(i) The treatment of neuromuscular, musculoskeletal, and related conditions through the use of chiropractic adjustment and manipulation; physical agent modalities;

physical therapeutics; manual, rehabilitative, and other therapeutic care; and mechanical, chemical, electrical, and thermal methods;

(ii) The use of acupuncture by a chiropractic physician who has completed two hundred fifty (250) hours of an accredited acupuncture course and has passed the National Board of Chiropractic Examiners Acupuncture Exam;

(iii) The location and removal of interference with nerve transmission and nerve function;

(iv) The making of appropriate referrals to other healthcare professionals for conditions that are outside the scope of practice of a chiropractic physician;

(v) The ordering of durable medical equipment for patients who need such equipment to assist in the restoration of their health under the plan of care for treatment of their neuromuscular, musculoskeletal, and related conditions; and

(vi) The provision of supportive care with due regard for nutrition, hygiene, sanitation, and rehabilitation designed to assist in the restoration and maintenance of a patient's health.

AND FURTHER AMEND by deleting Section 7 and substituting instead the following:

SECTION 7. Tennessee Code Annotated, Section 63-4-123(a)(1), is amended by deleting the subdivision in its entirety and substituting the following:

(1) The board shall adopt rules that establish minimum educational standards and criteria for chiropractic therapy assistants performing physical agent modalities, physical treatment, and clinical services that are within the scope of practice of a chiropractic physician and, under the supervision of a chiropractic physician, either in the office of the chiropractic physician or in the presence of the chiropractic physician at another location.

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Amendment No._____

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AMEND Senate Bill No. 1320 House Bill No. 519*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 11, Part 2, is amended by adding the following as a new section:

Notwithstanding any rule to the contrary, a nursing home, as defined in § 68-11-201, is authorized to participate in a drug donation repository program under title 63, chapter 10 until such time as the board for licensing health care facilities promulgates rules to effectuate such participation. Nothing in this title or title 63 precludes a nursing home from utilizing a drug donation repository program for drug disposal services.

SECTION 2. Tennessee Code Annotated, Title 68, Chapter 11, Part 2, is amended by adding the following as a new section:

(a) Notwithstanding this title or any rule, the board for licensing health care facilities is directed to use emergency rulemaking under § 4-5-208 to promulgate rules by January 1, 2018, to permit facilities licensed under this part to dispose of controlled substances and other prescription drugs by destruction using any means permitted by the federal drug enforcement administration.

(b) Notwithstanding this title or any rule, the board for licensing health care facilities is directed to use emergency rulemaking under § 4-5-208 to promulgate rules by January 1, 2018, to permit the disposal by donation or other means, including a drug donation repository program, of prescription drugs that are not controlled substances.

SECTION 3. Notwithstanding this act or the Uniform Administrative Procedures Act, compiled in Tennessee Code Annotated, Title 4, Chapter 5, any rule promulgated to implement

this act shall be provided to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate by the secretary of state, after approval by the attorney general and reporter, and at the same time the text of the rule is made available to the government operations committees of the senate and the house of representatives for purposes of conducting the review required by § 4-5-226 in order for the health committee of the house of representatives and the health and welfare committee of the senate to be afforded the opportunity to comment on the rule.

SECTION 4. This act shall take effect upon becoming a law, the public welfare requiring it.

House Health Subcommittee Am. #1

Amendment No._____

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Signature of Sponsor

AMEND Senate Bill No. 1032 House Bill No. 593*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Section 71-2-401(1), is amended by deleting the language "ten (10)" and substituting the language "five (5)".

SECTION 2. This act shall take effect July 1, 2017, the public welfare requiring it.

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Signature of Sponsor

AMEND Senate Bill No. 790 **House Bill No. 667***

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Section 63-5-115(d)(1), is amended by designating the existing language as subdivision (d)(1)(A) and adding the following language as a new subdivision (d)(1)(B):

(B) In addition to settings in which licensed and registered dental hygienists may engage in the provision of preventive dental care under the general supervision of a dentist and subject to the requirements imposed on those dental hygienists by subdivision (d)(1)(A), licensed and registered hygienists may also engage in the provision of preventive dental care for patients who are seventeen (17) years of age or less under the general supervision of a dentist through written protocol in a medical practice that contains a pediatrician. For the purposes of this subdivision (d)(1)(B), a pediatrician is a physician licensed under chapter 6 or 9 of this title whose medical practice is solely concerned with the primary care of children and is qualified for these endeavors due to intensive training devoted solely to all aspects of primary medical care for children, adolescents, and young adults.

SECTION 2. This act shall take effect July 1, 2017, the public welfare requiring it.

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Signature of Sponsor

AMEND Senate Bill No. 1238 **House Bill No. 766***

by deleting the language "under subdivision (d)(1), (d)(2), or (d)(3)" from subdivision (4) in Section 3 and substituting instead the language "under subdivision (d)(1) or (d)(2)".

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AMEND Senate Bill No. 597* House Bill No. 968

by inserting the language "as determined by rule," in subdivision (a)(3)(E) of the amendatory language of Section 1 between the language "not limited to," and "administration of".

AND FURTHER AMEND by deleting the language " whether the paid personal aide" in subdivision (a)(6) of the amendatory language of Section 1 and substituting instead the language " whether a paid personal aide".

AND FURTHER AMEND by deleting the language ", evaluated, and supervised" from subsection (b) of the amendatory language of Section 1.

AND FURTHER AMEND by deleting subsection (c) of the amendatory language in Section 1 and substituting instead:

(c) A paid personal aide may perform health maintenance tasks required by an individual receiving long-term supports and services and be paid to provide those tasks while performing services constituting home and community based long-term care, as defined in § 71-2-103, or under a private pay arrangement. Self-direction of healthcare tasks by an individual receiving medicaid-reimbursed home and community based long-term care services shall be provided pursuant to the Long-Term Care Community Choices Act of 2008, compiled in title 71, chapter 5, part 14.

AND FURTHER AMEND by adding the following language at the end of subsection (d) of the amendatory language of Section 1:

The requirements for documentation of the training required by this subsection (d) are to be determined by rule.

AND FURTHER AMEND by deleting Section 2 and substituting instead the following:

SECTION 2. The Tennessee commission on aging and disability shall, after consultation with the bureau of TennCare, the department of mental health and substance abuse services, the department of intellectual and developmental disabilities, AARP Tennessee, the Tennessee Disability Coalition, and the Tennessee Association of Home Care, promulgate rules implementing this act. These rules shall be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in Tennessee Code Annotated, Title 4, Chapter 5.

House Health Subcommittee Am. #1

Amendment No._____

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Signature of Sponsor

AMEND Senate Bill No. 268* **House Bill No. 1148**

by deleting Section 1 and substituting the following:

SECTION 1. Tennessee Code Annotated, Section 63-10-306, is amended by adding the following as a new subsection:

Any person licensed by the board of pharmacy under this section and holding a valid wholesaler license is considered to be licensed as a drug distributor until such a time when the board can promulgate rules to implement the third-party logistic provider (3PL) licensing process.

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AMEND Senate Bill No. 893* **House Bill No. 1149**

by deleting all language after the enacting clause and substituting the following:

SECTION 1. Tennessee Code Annotated, Section 68-3-502, is amended by adding the following as a new subsection (i):

(i)

(1) When a county medical examiner suspects that suicide may be a potential manner of death, the medical examiner is encouraged to consult the decedent's treating mental health professional, if known or applicable, prior to determination of manner of death.

(2)

(A) If, after inquiry by the county medical examiner pursuant to title 38, chapter 7, part 1, the deceased's next of kin disputes the manner of death determination on the death certificate, the next of kin may seek reconsideration of the manner of death determination.

(B) To seek reconsideration, the next of kin must submit a written request for reconsideration to the county medical examiner who signed the death certificate, the deputy state medical examiner of the regional forensic center where the autopsy was performed, and the commissioner of health, stating the nature and reasons for the reconsideration. If the county medical examiner who signed the death certificate is no longer the county medical examiner, then the notice shall be sent to the current county medical examiner instead. The written request for reconsideration must be submitted within one (1) year of the date the death certificate is

filed with the office of vital records and must be supported by a signed affidavit.

(3) Within thirty (30) days after receiving notice of the reconsideration request, the county medical examiner shall meet with the requesting next of kin. The meeting shall be either in person or via teleconference, at the discretion of the requesting next of kin. At the meeting, each party shall present the reasons supporting their position with respect to the manner of death, including any relevant documentation. The county medical examiner shall make a written determination on the reconsideration within thirty (30) days after the reconsideration meeting and shall notify the requesting next of kin, the deputy state medical examiner of the regional forensic center where the autopsy was performed, and the commissioner of health in writing. If the medical examiner who signed the medical certification is no longer in a position as county medical examiner, then the current county medical examiner shall participate in the reconsideration meeting and issue the written determination on the reconsideration instead.

(4) If, after reconsideration, the county medical examiner finds a change in the manner of death determination is warranted, the county medical examiner shall file an affidavit within thirty (30) days directing the office of vital records to issue an amended death certificate to reflect the county medical examiner's findings as to manner of death.

(5)

(A) If, after reconsideration, the determination of manner of death is still disputed by the requesting next of kin, the requesting next of kin may seek further review of the determination by petitioning the deputy state medical examiner for the regional forensic center in which the autopsy was performed, on a form prescribed by the department of health, to review the medical records, hospital records, death certificate,

investigative reports, and any other documentary evidence deemed necessary of the deceased. The deputy state medical examiner for the regional forensic center shall respond to the requesting next of kin detailing the findings within thirty (30) days with a written report. The report shall state whether the deputy state medical examiner agrees with the determination of manner of death on the death certificate, and, if the deputy state medical examiner for the regional forensic center disagrees with the determination of manner of death on the death certificate, the report shall detail those findings and the basis for the disagreement. The report shall be sent to the next of kin and the commissioner of health.

(B) If the deputy state medical examiner finds a change in the manner of death determination is warranted, the deputy state medical examiner shall file an affidavit within thirty (30) days directing the office of vital records to issue an amended death certificate to reflect the deputy state medical examiner's findings as to manner of death.

(6)

(A) If, after review by the deputy state medical examiner for the regional forensic center, the determination of manner of death is unchanged, then the requesting next of kin may seek mediation with the deputy state medical examiner for the regional forensic center with a Rule 31 mediator under the Rules of the Supreme Court of Tennessee, at the sole expense of the requesting next of kin.

(B) If the deputy state medical examiner finds a change in the manner of death determination is warranted following mediation, the deputy state medical examiner shall file an affidavit within thirty (30) days directing the office of vital records to issue an amended death certificate to reflect the deputy state medical examiner's findings as to manner of death.

(7) The department of health shall maintain a notice of decedents' next of kin rights with regard to this subsection (i) on its public website.

(8) As used in this subsection (i), "next of kin" means the person who has the highest priority pursuant to § 62-5-703.

SECTION 2. This act shall take effect upon becoming a law, the public welfare requiring it.